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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/008,778	11/13/2001	Eric Hauser Kuhrts	68911-076	4731

7590 05/13/2009

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EXAMINER	
MELLER, MICHAEL V	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
05/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/008,778	KUHRTS, ERIC HAUSER	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16 and 18-27* is/are pending in the application.

4a) Of the above claim(s) *1-12,14,16 and 18-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Any rejection not reiterated is hereby dropped.

Election/Restrictions

The restriction requirement of record is maintained for the reasons of record. Claims 1-12, 14, 16, 18-27 are withdrawn from further consideration since they are drawn to non-elected subject matter. The restriction requirement has already been made **FINAL** as noted by applicants.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for the claimed bioavailable pharmaceutical composition comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with this claim.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art;

With respect to the Wands factors above (particular as they pertain to the quantity of experimentation necessary as well as the state of the prior art within the medical field), Applicants have not reasonably demonstrated/disclosed that the

claimed extract composition has the claimed therapeutic quantity. There is no way for one of ordinary skill in the art to reasonably calculate if the claimed extract is enabled or not. The ratios are very ambiguous and hard to quantify against the prior art.

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to calculate the instantly claimed extract composition's effective amounts in a manner so as to provide the functional effect instantly claimed. Such a ratio leads to ambiguity and ambiguity is not helpful when trying to understand how to make and use the invention. When using such ratios to express the amount of components in the hops extract, the extract reads on any hops extract. In fact the ratio is so confusing it claims the invention in functional language instead of language which actually defines the active components in the extract which the invention is interested in.

The specification uses the language of the claims and thus the specification only provides the guidance that the claims reflect. Thus, there is nothing else for one of ordinary skill in the art to turn to in an effort to understand the claims. While applicant has amended the claims to recite amounts, these amounts are in terms of a dose which is not recited in the claims.

It is still not clear on the record what is meant by the claimed bioavailable pharmaceutical composition comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about

3.33 with reduced gastrointestinal and cardiovascular toxicity for the above reasons and applicant has offered no explanation.

In an effort to remedy this issue, applicant amended the claim to recite that "the dose of the COX-2 inhibitor ranges from about 5 mg to about 1,000 mg per day" but this still does not clear up the above addressed problems, in fact it has confused them further. It is not clear what "the dose" refers to since there is no antecedent basis for this term in the claim.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is vague and indefinite since it is not clear what is meant by the claimed bioavailable pharmaceutical composition comprising a therapeutic quantity of a COX-2 inhibitor having an IC50-WHMA COX-2/COX-1 ratio ranging from about 0.23 to about 3.33 with reduced gastrointestinal and cardiovascular toxicity. What is this saying ? It is not clear how to quantify the claimed ratio. How does one compare the prior art against such a claim which uses no percentages or amounts that are actually tangible. The ratio

uses functional language which is not definite and thus cannot be a meaningful limitation.

In an effort to remedy this issue, applicant amended the claim to recite that "the dose of the COX-2 inhibitor ranges from about 5 mg to about 1,000 mg per day" but this still does not clear up the above addressed problems, in fact it has confused them further. It is not clear what "the dose" refers to since there is no antecedent basis for this term in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rigby et al. (US 3354219) in view of Todd, Jr. et al. (US 5041300) and as evidenced by Medicinenet.com and About.com.

7. Rigby teaches that hot water, NaOH, and hops are boiled for two hours, see col. 4, lines 5-70. The reference also notes that KOH (potassium hydroxide) can be used instead of NaOH. It is noted that the composition has a milder odor and flavour thus someone drank the composition. Medicine net makes it clear that acute pain comes on quickly thus it reads on anyone since anyone can have acute pain. About.com makes it clear that standarized extracts have been processed to contain a specific amount of a compound but as see in Rigby once the extract is reacted with the KOH a specific amount of iso-alpha acids are formed, namely 2.4 g of isohumulones, see col. 4, lines 15-25.

8. Rigby does not teach the claimed amount of COX-2 inhibitor.

9. Todd teaches that 50 ppm of isoalpha acids were added to beer, see col. 13, lines 25-40.

In the event that using the KOH instead of NaOH is seen as obviousness instead of anticipation, (which this examiner highly doubts) it still would been obvious to one having ordinary skill in the art to use the KOH instead of the NaOH since Ribgy clearly indicates that "obvious commercial alternatives are possible" and then goes on to list KOH as one of the options. Clearly the KOH was envisioned to be used instead of the NaOH.

Further it would have been obvious to use the claimed amount of COX-2 inhibitor since Todd makes it clear that 50 ppm of isoalpha acids were added to beer to yield beneficial results, see col. 13, lines 25-40 of Todd. This translates to 50 mg/liter which clearly would provide motivation for one of ordinary skill in the art to use the iso alpha

acids of Rigby at a concentration of 5 mg to 1,000 mg per day since in Rigby one is consuming beer as they are in Todd and 3 beers would be equivalent to one liter which would equate to 50 mg. One beer would equate to 17.75 mg which is well within the claimed range as well. Thus, the claimed invention is obvious.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/
Primary Examiner, Art Unit 1655